– Translation from the French –

(19) FRENCH REPUBLIC

NATIONAL INDUSTRIAL PROPERTY INSTITUTE

PARIS

(11) **Publication No.:** 2 692 471
(to be used only in requests for copies)

(21) **National Reg. No.:** 92–07504

(51) Int. Cl[5]: **A 61 B 17/58**

(12) **PATENT APPLICATION** A1

(22) **Filing date:** June 19, 1992 (19.06.92)

(30) **Priority:** *[blank]*

(43) **Application disclosure date:** December 24, 1993 (24.12.93), in issue No. 93/51 of the *Bulletin.*

(56) **List of documents cited in the preliminary search report:** *See the end of the present document.*

(60) **References to other related French documents:** *[blank]*

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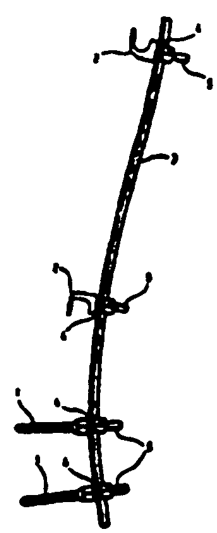
(54) **Device for treatment of the spine.**

(57) The present application relates to a device for treatment of the spine. This device includes elements for anchoring the vertebrae, of the type consisting of bone screws [1] or hooks [2] and includes a solid threaded metal portion [5], a smooth shaft [3] having a circular cross-section, and slideways [4] that freely receive the shaft and that are secured to the said shaft when a nut on the threaded portion is tightened.

Such a device allows a significant saving of time during installation on the patient.



FR 2 692 471 – A1 *[bar code]*

The present invention relates to a device for treatment of a spine having an abnormal deviation caused by degeneration or trauma.

Numerous devices are already known whose purpose is to treat vertebral arthroses or fractures, or for correcting deviations of the spinal column, such as scoliosis, lordosis, and kyphosis.

These existing known devices generally include elements for anchoring the said devices in the vertebrae, such as bone screws or hooks; an element for linking the various anchoring elements, which linking element may consist of a shaft or a perforated metal plate; and a device for joining each anchoring element to the linking element.

However, the devices in question offer only partial fulfillment of a certain number of often contradictory requirements.

Simultaneously, the said devices must be capable of rapid installation; they must consist of the smallest possible number of standardized elements; they must not require an excessive amount of work in order to be installed on the vertebrae; and their dimensions must be as small as possible.

The goal of the device according to the present invention is to provide a better response to all of these requirements. The device is based on the concept of the reduction of deformations. Thanks to its simplicity and ease of installation, it saves precious time during installation while offering a very high degree of safety.

It includes elements that allow the device to be anchored in the vertebrae; a shaft that links the various anchoring elements; and a device for joining each anchoring element to the shaft. The device is characterized by the fact that each of the elements that allow the device to be anchored in the vertebrae includes a solid metal portion with external threads, equipped with a nut that can be tightened until it reaches a stop plate; by the fact that the linking shaft is a smooth shaft having a circular cross-section; and by the fact that the joining device is a metal slideway that freely receives the shaft and whose two ends, which are folded back on each other, have a bored hole, whose axis is perpendicular to the axis of the channel through which the shaft slides, in order to receive the threaded metal portion of an anchoring element, such that the tightening of the nut on the said threaded metal portion – after the threaded metal portion has been introduced into the bored holes in the said ends, and until the said ends are securely pressed against the stop plate – causes the slideway to be clamped securely around the shaft, due to the deformation of the channel through which the shaft slides.

Such a device allows the use of a shaft, or of several shaft sections, whose curvature is suitable for the vertebral region to be treated.

The slideways are easily installed on the shaft, because they are placed on the shaft at either end of the shaft and slide freely along the shaft, regardless of the curvature of the shaft.

The principle behind the reduction of a deformed spine is three-dimensional. A scoliotic curve, oriented in a plane close to the frontal plane, must be transformed into a physiological curve that is located in the sagittal plane and that has a normal kyphotic, thoracic, and lumbar lordotic curvature.

Via the anchor points, the shaft imprints its own shape on the spine to be reduced. The shaft is placed in position along the above-mentioned physiological sagittal curvatures. It is installed along the patient's sagittal plane. The anchor points nearest to the shaft are then engaged and locked, in order to hold the shaft in the sagittal plane and prevent its rotation. The anchor points that are located farthest away, in the concavity of the curve, are engaged thanks to the length of the threaded shaft of each anchor point. Once the threaded shaft passes through the bored hole in the connecting part, the gradual tightening of the nut brings the anchor point on the shaft closer, along the axis of the threaded shaft, thus producing the optimal reduction. If the elasticity of the spine is exhausted, the shaft is deformed and remains in an intermediate position somewhat short of the maximum reduction.

Accordingly, the device according to the invention allows the intermediate anchoring elements to be installed *in situ*, and allows each of their threaded metal portions of these anchoring elements to be introduced into the threaded hole in a slideway, so that the intermediate anchoring elements can be secured rigidly to the shaft, in alignment with the upper and lower anchoring elements, so as to obtain the desired correction of the connected vertebrae via the installation and tightening of the nuts, which actions cause the slideways to be clamped securely around the shaft.

The device that is the subject of the invention can be installed on the spine of the patient in either the anterior or posterior position in relation to the spine.

Furthermore, the device according to the invention can be installed within a period of operating time that is significantly shorter than the operating time required for the installation of previously known spinal correction devices, thanks to the increased ease with which the surgeon can thread the solid cylindrical portions of the anchoring elements through the slideways and secure them to the shaft, i.e., by tightening a nut along the axis of an anchoring element, with the aid of a simple screwdriver.

The present invention will now be described with the aid of a specific embodiment, as illustrated in the attached drawings, on which:

- Figures 1 and 2 are side views, at an angle of 90° from each other, of a single device according to the invention;
- Figures 3 and 4 represent, respectively, a bone screw and a hook, which are used as anchoring elements in the device shown in figures 1 and 2;
- Figures 5 and 6 represent, respectively, a top view and a side view of the slideway used in the device shown in figures 1 and 2;
- Figures 7, 8, and 9 represent variants of the slideways that can be used in the device according to the invention. The surface that comes into contact with the stop plate of the anchoring system is provided with star-shaped anti-rotation means;
- Figures 10 and 11 represent, respectively, a side view and a front view of a sacral bearing plate that can be used as an anchoring element in the device according to the invention;
- Figures 12 and 13 represent, respectively, a side view and a front view of a plate that rests on the body of a vertebra, and that can be used as an anchoring element in the device according to the invention; and, lastly,
- Figures 14 and 15 represent, respectively, a front view and a side view of a stabilization system intended for use with two shafts, which system includes a brace, stay, or strut and two slideways.

The device shown in figures 1 and 2 includes anchoring elements such as bone screws [1] or hooks [2]; a linking shaft [3], and devices for joining each anchoring element to the shaft, which devices consist of slideways [4].

Each anchoring element consists of a single part having a solid cylindrical metal portion [5] provided with external threads [6], and includes a stop plate [7] that limits the tightening of a nut [8] on the said external threads.

As shown in Figure 3, the stop plate [7] for a bone screw [1] to be implanted in the pedicle or lamina of a vertebra may consist of the surface of the bone screw, which surface is perpendicular to the axis of the head [9] of the said bone screw, and opposes the pitch of the bone screw [10]. It should be noted that the axis of the threaded metal portion [5] is the same as the axis of the pitch of the bone screw [10].

As shown in Figure 4, the stop plate [7] of a hook [2] intended to be hooked into the pedicle of a vertebra may consist of the rear wall of the hook, perpendicular to the axis of the threaded metal portion [5], which wall serves as a stop plate and is also provided with star-shaped anti-rotation means [37].

The linking shaft [3] of the device according to the invention is a smooth shaft with optimal elasticity and a circular cross-section. It can be cambered or curved in accordance with the shape that is desired for the portion of the spinal column to be treated.

Slideways [4] can slide along the shaft [3], either freely or by friction.

The slideways [4], shown on figures 1 and 2 and in greater detail in figures 5 and 6, are in the form of a metal part whose ends [11] [12] are folded back on each other so as to form a channel [13] corresponding to the diameter of the shaft. Each of the ends [11] [12] of the slideway has a bored hole [14] [15] whose axis is perpendicular to the axis of the channel [13] and whose diameter allows the threaded metal portion [5] of an anchoring element to be received. The bored holes [14] [15] are located opposite each other, such that they have the same axis.

When the threaded metal portion [5] of an anchoring element [1] [2] is introduced into the two bored holes [14] [15] of a slideway [4], and when the nut [8] is tightened until the two flat ends [11] [12] of the slideway [4] are securely pressed against the stop plate [7], the two ends [11] [12] of the slideway are brought together. This action reduces the diameter of the channel [13], thereby causing the slideway [4] to be clamped securely around the shaft [3].

The slideways used in the device that is the subject of the present invention may take several forms.

A first variant, shown in Figure 7, has a so-called "double" slideway [4'], which differs from the slideway shown in figures 5 and 6 only in that the length of the variant, in the direction of the axis of the channel that receives the shaft, is twice the length of the slideway shown in figures 5 and 6, and in that it has a curved slot [19] that extends from the edge of the ends [11] [12] to a point short of the expanded portion that delimits the channel [13]. As likewise shown in Figure 7, each of the ends [11] [12] of the said slideway may have two bored holes [14] [15] or [16] [17] that receive a screw and a forcing nut [1] [2] *[sic]*. Such a variant, which therefore consists of a double slideway with a curved slot [19], allows two shafts with different curvatures to be joined end-to-end for the treatment of a patient's spine.

A second variant, shown in Figure 8, has an open slideway [4''], which differs from the slideway shown in figures 5 and 6 in that its two ends [11] [12] form an integral unit and in that it has a

slot [18] along one side of the channel [13], which slot [18] allows the shaft [3] to be force-fitted onto the slideway Such a variant allows a slideway to be installed at an intermediate point on the shaft without requiring the slideway [4''] to be introduced at either end of the shaft.

A third variant, shown in Figure 9, consists of another open slideway [4''']. This slideway is in the form of a metal block whose dimensions are those of a parallelepipedal rectangle that is divided axially by an upwardly extending slot [20] that starts at an essentially circular opening [21], which is preferably notched. The said slot defines a channel [13] for receiving a shaft [31] and terminates at a blind end [21], so as to form two ends [11] [12] that constitute an integral unit. Each of the said ends [11] [12] of the slideway has a bored hole [14] [15] that is analogous to the bored holes in the slideways shown in figures 5 through 8.

The device according to the invention may include one or more bone screws or hoots, depending on the number of vertebrae to be treated, and one or more shafts, depending on the nature and amplitude of the deviation of the spine to be treated, with the understanding, of course, that the number of slideways employed will be identical to the number of anchoring elements employed.

Other anchoring systems may also be utilized in the device according to the invention. Such systems include, for example, the sacral bearing plate shown in figures 10 and 11, or the plate that rests on the body of a vertebra, as shown in figures 12 and 13.

The sacral bearing plate [22] is in the form of an elongated plate that includes, in its central region, a solid cylindrical portion [5] with external threads [6], and that also includes, at one of its ends [23], whose thickness is reinforced, a bored hole [24] that receives the head of a standard bone screw intended to be installed in the pedicle of the S1 [first sacral] vertebra, and, at its other end [23'], two other bored holes [25] [26], that receive the heads of standard bone screws installed in the sacrum. The downwardly shifted position of the solid cylindrical portion [5] with external threads [6], below the position of a pedicle screw installed in the S1 vertebra, enables a short connection (L5–S1 assembly) with a pedicle screw installed in L5 [i.e., the 5th lumbar vertebra].

The axis of the threaded cylindrical portion [5] is perpendicular to the surface of the plate with which it forms an integral whole, and the said surface serves as a stop plate [7] for a nut [8] that is screwed onto the said cylindrical portion. The installation of the said [cylindrical] portion is shifted by approximately 15 mm in relation to the S1 screw.

As shown in Figure 11, the axis of the bored hole [24] is perpendicular to the plane of the lower and upper surfaces of the plate [22] that is secured by screws to the S1 pedicle, and is parallel to the axis of the solid cylindrical portion [5]. However, the axis of the bored holes [25] [26]

is oblique, so as to orient outwardly the bone screw contained therein, thereby facilitating the installation of the plate [22] on the sacrum via the sacral wing.

The solid cylindrical portion [5] with external threads plays the same role as the threaded portion [5] of the anchoring elements shown in figures 3 and 4.

The plate [27] that rests against the body of a vertebra is a rigid plate, usually oval in shape, whose two parallel surfaces (i.e., the lower surface and the upper surface) are curved slightly inward, as shown more specifically in Figure 12, so as to follow the shape of the body of the vertebra.

This plate [27] includes, in its central region, a solid cylindrical portion [5] with external threads [6], whose axis is perpendicular to the convex surface, which serves as a stop plate for a nut [8] that is screwed onto the said portion [5].

The plate [27] also has two spherical bored holes [28] [29], which are located on either side of the solid threaded portion [5]. The said bored holes, both of which are essentially spherical, receive the head (which has a complementary spherical shape) of a standard bone screw [36], as shown in Figure 12.

It should be noted that, regardless of the anchoring element of which it forms a part, the solid cylindrical portion [5] with external threads according to the present invention may include, in its threaded portion, a region [30] having a reduced cross-section, which region is intended to be cut after the said threaded portion has passed through the ends of a slideway [4] [4'] [4''] [4'''] and after a nut [8] has been affixed and tightened.

In view of the fact that the device according to the invention may include two shafts [3], one of which is located on each side of the spinal apophysis of the vertebrae, so as to provide better support for, and correction of, a patient's spine, the two said shafts [3] may advantageously be joined together via one or more transverse stabilization systems, as shown in figures 14 and 15.

The said stabilization system includes a dumbbell-shaped brace or strut [31], each of whose two ends includes a tapped or threaded hole [32] [33], and two slideways [4] [4'] [4''], or preferably slideways [4'''], as shown in Figure 9, that are threaded respectively onto each of the shafts [3] intended to be joined, which slideways can be secured by a suitable screw [34] [35], as shown more specifically in Figure 15.

CLAIMS

1. Device for treatment of the spine, including elements [1] [2] [22] [27] for anchoring the said device in the vertebrae; a shaft [3] that links the said various anchoring elements, and a device for joining each anchoring element to the shaft, characterized in that each of the elements [1] [2] [22] [27] for anchoring the said device in the vertebrae includes a solid cylindrical portion [5] with external threads [6], which cylindrical portion is provided with a nut [8] that can slide as far as a stop plate [7]; in that the shaft [3] is a smooth shaft with a circular cross-section and a suitable degree of elasticity; and in that the joining device is a metal slideway [4] [4'] [4''] [4'''] that freely receives the shaft [3] and whose two ends [11] [12], which are folded back on each other, have a bored hole [14] [15], whose axis is perpendicular to the axis of the channel [13] through which the shaft slides, in order to receive the threaded metal portion of an anchoring element, such that the tightening of the nut [8] on the said threaded metal portion [5] until the two ends of the slideway [4] are securely pressed against the stop plate [7] causes the slideway [4] to be clamped securely around the shaft, as a result of the deformation of the channel [13] through which the shaft [3] slides.

2. Device according to Claim 1, characterized in that the said device includes, as an element for anchoring the said device to the vertebrae, one or more bone screws [1] in which the axis of the bone screw is the same as the axis of the threaded metal portion [5], and the stop plate [7] consists of the face of the head [9] of the bone screw, which face is perpendicular to the said axis and opposes the pitch of the bone screw.

3. Device according to Claim 1, characterized in that the said device includes, as an element for anchoring the said device to the vertebrae, one or more hooks [2] in which the rear wall of the hooks, which rear wall is perpendicular to the axis of the threaded metal portion [5], serves as the stop plate [7] for the nut [8].

4. Device according to any one of claims 1 through 3, characterized in that the shaft [3] is cambered or curved, in order to impart to it the desired shape for the corresponding portion of the spine to be treated.

5. Device according to any one of claims 1 through 4, characterized in that the slideway [4'] is a so-called "double" slideway, whose length, in the direction of the axis of the channel [13] that receives the shaft [3], allows the end-to-end joining of two shafts [3] having different curvatures, for the separate treatment of complex deformations involving two curvatures of the spine of the patient, and also allows the alignment of the said two shafts

on the double slideway, with each of the ends [11] [12] of the slideway optionally also having two bored holes [14] [15] and [16] [17], which bored holes are separated by a curved slot [19] for receiving the threaded metal portion [5], so that the said slideway [1] [2] [22] [27] *[sic]* can be tightened.

6. Device according to any one of claims 1 through 5, characterized in that the slideway [4''], whose two ends [11] [12] form an integral unit, also has a slot [18] along one side of the channel [13], which slot [18] allow the shaft [3] to be force-fitted at an intermediate point.

7. Device according to any one of claims 1 through 6, characterized in that the said device includes, as an element for anchoring the said device to the vertebrae, a sacral bearing plate [22] that has an elongated shape and that includes, in its central region, a solid cylindrical portion [5] with external threads [6], and that also includes, at one of its ends, the thickness of which end is reinforced, a bored hole [24], and, at its other end, two other bored holes [25] [26] that receive the heads of standard bone screws [36].

8. Device according to any one of claims 1 through 7, characterized in that the said device includes, as an element for anchoring the said device to the vertebrae, a plate [27] that rests against the body of a vertebra, which plate is oval in shape and curves inward, and which includes, in its central region, a solid cylindrical portion [5] with external threads [6], and, on either side of the said shaft *[sic]*, two spherical bored holes [28] [29] that receive the heads of the bone screws.

9. Device according to any one of the foregoing claims, characterized in that the said device includes two smooth shafts, along with their respective anchoring elements and slideways, which two shafts [3] are joined, so as to form an integral unit, by one or more stabilization systems, each of which stabilization systems includes a brace or strut [31] that is provided with two tapped or threaded holes [32] [33] and two slideways [4] [4'] [4''] [4'''] that are secured by screws [34] [35].

10. Device according to any one of the foregoing claims, characterized in that the said solid cylindrical portion [5] with external threads [6] of the anchoring element [1] [2] [22] [27] includes a region [30] with a reduced cross-section, whose purpose is to facilitate the breaking of the said solid cylindrical portion.

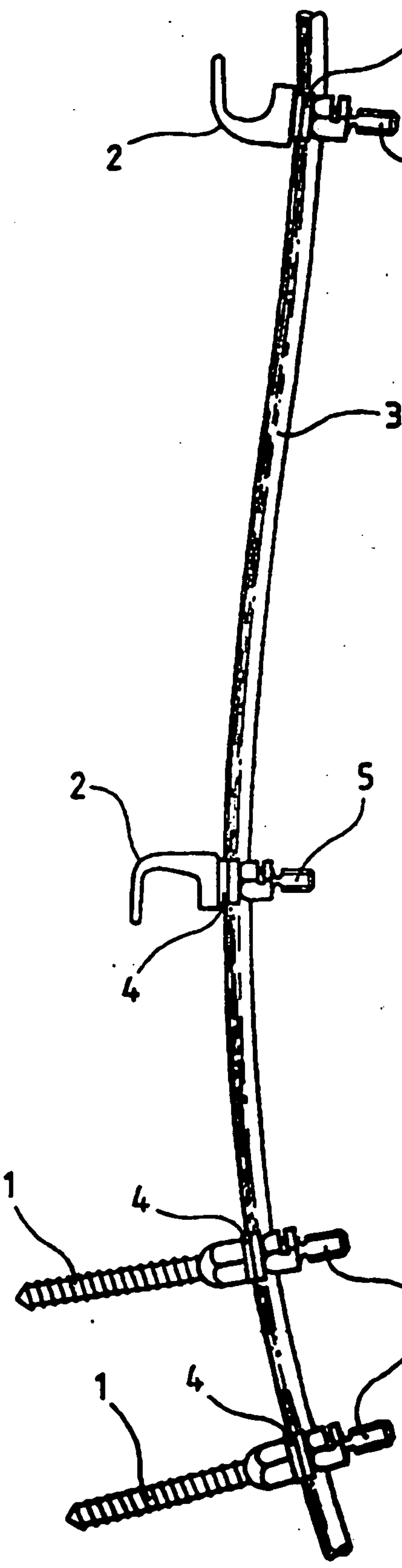


Fig.1

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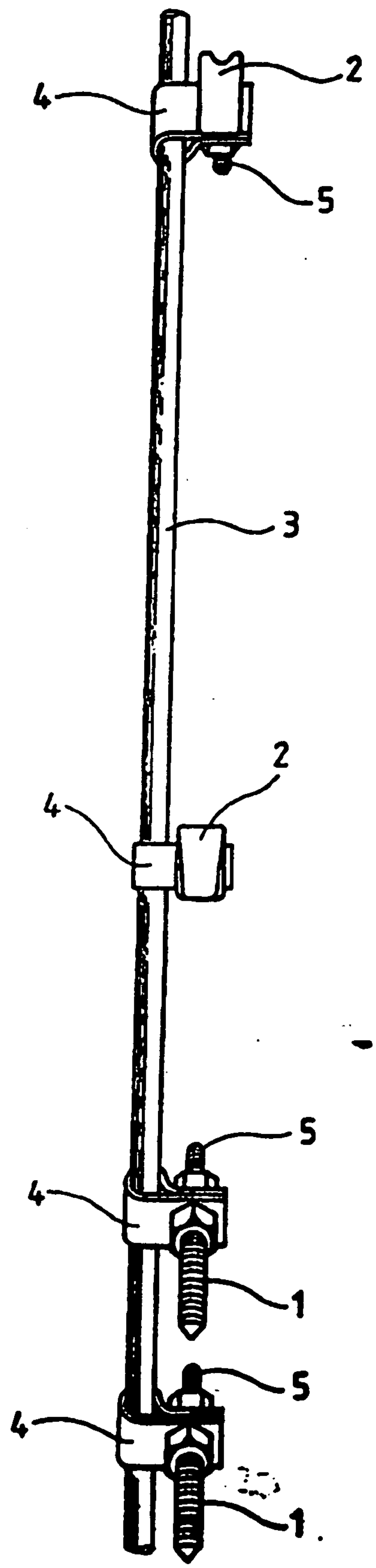

Fig.2

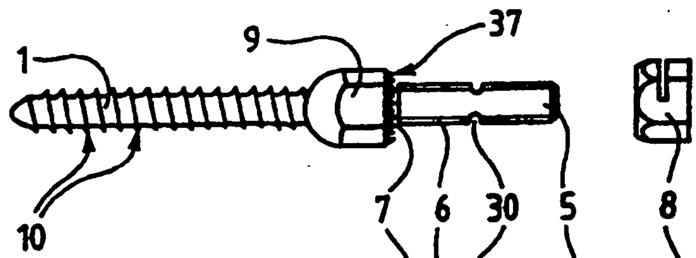

Fig.3

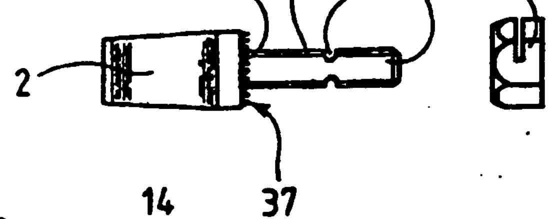

Fig.4

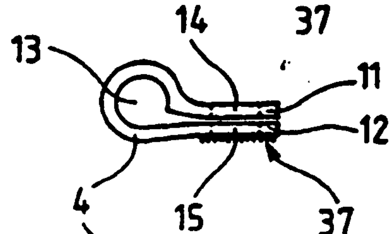

Fig.5

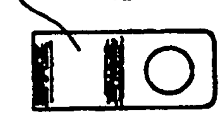

Fig.6

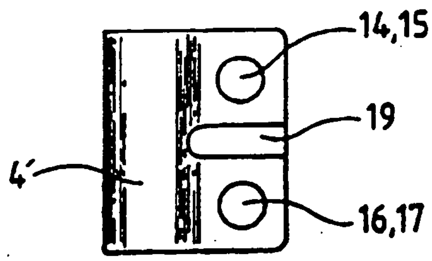

Fig.7

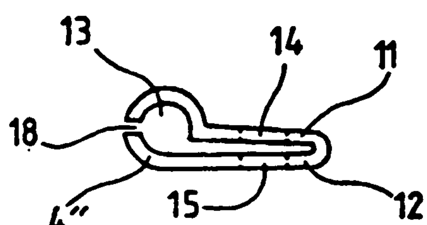

Fig.8

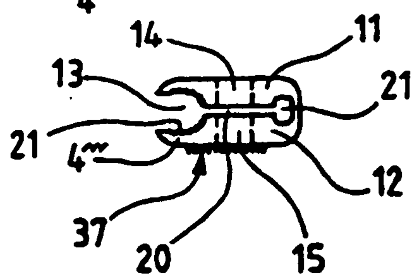

Fig.9

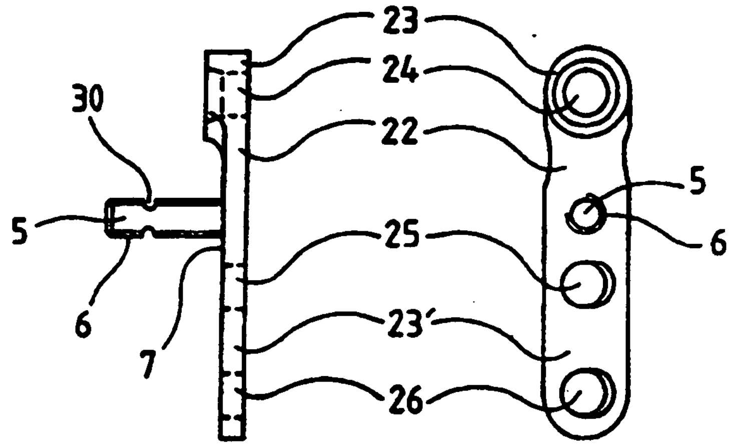

Fig.10

Fig.11

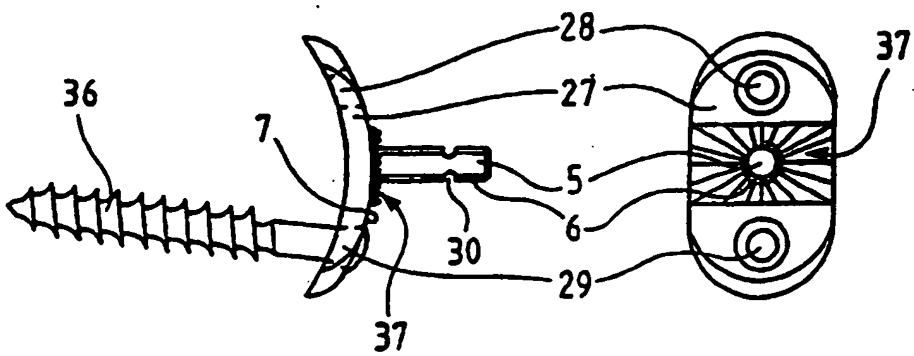

Fig.12

Fig.13

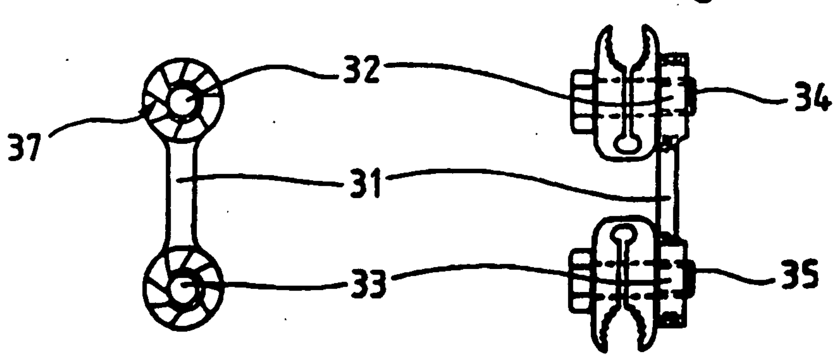

Fig.14

Fig.15

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2 692 471
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FR 92-07504
FA 472737

SEARCH REPORT

Prepared according to the most recent claims filed before the start of the search.

DOCUMENTS CONSIDERED RELEVANT		Affected claims in the examined application
Category	Document citation, with an indication, as necessary, of the pertinent portions	
Y	EP–A–0 408 489 (Gebrüder Sulzer) * column 2, line 28 – line 49 * * figure 2 * -----	1–2, 4
Y	US–A–4 648 388 (A.D. Steffee) * abstract; figure 5 * * column 4, line 24 – line 55 * -----	1–2, 4
A	US–A–4 773 402 (M.A. Asher and W.E. Strippgen) * figure 1 * -----	3–4, 7
A	FR–A–2 615 095 (Société de Fabrication de Matériel Orthopédique) * figures 3 – 5 * -----	8
A	EP–A–0 383 992 (Acromed) * figures 10 – 12 * -----	9
A	WO–A–8 701 026 (S. Olerud) * page 7, line 12 – line 14; figure 1 * -----	10

TECHNICAL FIELDS SEARCHED (International Class 5)

A 61 B

Search completed on (date): February 18, 1993

Examiner: P. Nice

CATEGORIES OF THE CITED DOCUMENTS

X: Particularly pertinent, in and of itself
Y: Particularly pertinent, in combination with another document in the same category
A: Pertinent to at least one claim, or to the overall technological background
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P: Intercalary [i.e., inserted] document

T: Theory or principle behind the invention
E: Patent document bearing a date prior to the filing date, and which was published only on that filing date or on a later date
D: Cited in the application
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&: Member of the same family; corresponding document